

### **REMARKS/ARGUMENTS**

The rejections presented in the Office Action dated April 16, 2007 (hereinafter Office Action) have been considered. Claims 1-19 and 30-36 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1 and 30 have been amended. Support for the amendment to claims 1 and 30 can be found in dependent claim 14. Because the subject matter added to the independent claims was already present in the claims, and therefore previously considered and searched, no new search is necessitated by the amendments. Furthermore, no new matter is added.

Claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Reg. No. 30,750 to *Diack et al.* (hereinafter "*Diack*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Diack* does not teach each and every element of independent claims 1 and 30, and therefore fails to anticipate these claims.

The Applicant's independent claims 1 and 30 each recite, among other features, some variation of detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources, receiving information associated with a non-electrophysiological cardiac source, and separating a signal from the composite electrical signal using source separation.

*Diack* discloses a cardiac resuscitator and monitoring apparatus. (Abstract). *Diack's* apparatus senses EKG information (Col. 17, Line 44). The Examiner identifies element 110 of Fig. 14 (element 110 being a band pass filter) and Col. 18, Line 66 as teaching detecting

a composite electrical signal and separating a signal from the composite signal. The Applicant respectfully submits that *Diack's* disclosure as a whole, even in the cited portions, does not provide a teaching of source separation. The Applicant respectfully submits that *Diack* does not contemplate using source separation, and describes methods which are different from source separation methods.

One of ordinary skill in the art would understand that band pass filtering techniques are different from signal source separation techniques. Band pass filtering filters out specified lower and higher frequencies components from a signal. Band pass filtering is different than separating a specific signal from a composite signal, the signals being separated according to their sources. Band pass filtering techniques operate by using the various frequencies in a signal while source separation techniques operate by separating signals according to their respective source origins.

Therefore, the Applicant respectfully submits that *Diack* does not teach separating a signal from the composite electrical signal using source separation, as recited in independent claims 1 and 30.

The Applicant's independent claims 1 and 30 each further recite, among other features, some variation of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

*Diack's* apparatus uses a microphone for sensing respiration sounds. (Col. 19, Lines 39-50, discussing Fig. 14, referenced by the Examiner). "The microphone is employed for ascertaining bodily movement or physical activity, and in particular for ascertaining respiration sound." (Col. 19, Lines 44-47).

*Diack's* apparatus uses both sensed EKG signals and respiration sounds to select an appropriate therapy from several therapy options. (See Table 1, as cited by the Examiner). Specifically, if normal respiration and EKG patterns are sensed, then no action is taken (first line of Table I); if heart activity is sensed with no respiration, then a defibrillation therapy is applied (second line of Table I); and if heart rhythm and respiration are not sensed

(indicating cardiac arrest) then pacing is applied (third line of Table I). (See Col. 18, Lines 20-33).

*Diack* does not disclose that any of the sensed signals are used to verify another signal. Instead, as illustrated by Table I, the similarities and differences between the signals are used to trigger various therapies. The Applicant respectfully submits that considering both EKG and respiration signals in selecting a therapy does not constitute either of the signals validating the other, particularly not confirming or rejecting a signal as actually being a separated cardiac signal. Accordingly, the Applicant respectfully submits that *Diack* does not teach verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in independent claims 1 and 30.

For each of the reasons discussed above, the Applicant respectfully submits that *Diack* fails to teach each and every element and limitation of at least independent claims 1 and 30, and therefore cannot anticipate these claims.

Dependent claims 4, 7, 8, 10, 16-19, 31, and 34-36, which are dependent from independent claims 1 and 30, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Diack*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 30. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 4, 7, 8, 10, 16-19, 31, and 34-36 are also not anticipated by *Diack*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 4, 7, 8, 10, 16-19, 30, 31, and 34-36 as being anticipated by *Diack* is not sustainable, the withdrawal of which is respectfully requested.

Claims 1-19 and 30-36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,388,578 to *Yomtov et al.* (hereinafter “*Yomtov*”) in view of U.S. Publication No. 2005/0240234 by *Joo et al.* (hereinafter “*Joo*”). Dependent

claims 14 and 15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Yomtov* in view of *Joo*, as applied to independent claim 1, and further in view of U.S. Publication No. 2003/0032889 by *Wells* (hereinafter “*Wells*”).

The Applicant’s independent claims 1 and 30 each recite, among other features, some variation of detecting a composite electrical signal at a subcutaneous non-intrathoracic location, the composite electrical signal associated with a plurality of sources, receiving information associated with a non-electrophysiological cardiac source, and separating a signal from the composite electrical signal using source separation.

*Yomtov* discloses an implantable cardiac monitor. The Examiner identifies element 96 (an R wave detector), Col. 17, Line 40, and Figs. 8A-B of *Yomtov* as disclosing separating a signal from the composite signal and verifying that the separated signal is a cardiac signal using a second cardiac source signal. (Page 4).

The Applicant respectfully submits that it is unclear which methodology of *Yomtov* is being interpreted as constituting performing separation of signal. Even so, source separation is not contemplated by *Yomtov*. The Applicant refers to the above discussion concerning the understanding of source separation as a particular methodology that separates one or more signals from a composite signal, the separation being performed according to the source of the particular signal. A review of *Yomtov* fails to identify any disclosure of source separation techniques.

Although the Examiner does not rely on the *Joo* reference to teach or suggest separating a signal from the composite electrical signal using source separation methodologies, a review of the *Joo* reference fails to identify such a teaching or suggestion. Therefore, the Applicant respectfully submits that the combination of *Yomtov* and *Joo* fails to disclose separating a signal from the composite electrical signal, as recited in independent claims 1 and 30.

The Applicant’s independent claims 1 and 30 each further recite, among other features, some variation of verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

It appears that in addressing the above claim limitations on Page 4 of the Office Action, the Examiner relies on the following passage of *Yomtov*:

In performing step 178 to determine if a valid beat had been detected, the microprocessor utilizes the following criteria. If both the first and second channels contained noise, the microprocessor will determine that a reliable beat classification cannot be performed. If the microprocessor detected that there was noise in one channel and was unable to verify a detected QRS complex in the other channel, it will determine that a valid beat had not been detected.

The Applicant respectfully submits that it is unclear from the passage above which of the first and second channels is considered by the Examiner to contain a signal separated from a composite signal. Even so, neither of these channels is used to verify the other channel as a separated cardiac signal. Although each channel is “verified” as containing a heart beat, *Yomtov* appears to verify each channel independently of the other using thresholds. For example, when discussing the verification methods of Figs. 8A-B, *Yomtov* states that:

if there was noise in the first channel, the microprocessor then proceeds to step 174 to verify that the data stored in the random access memory 84 and obtained from the second channel indicates that there was a valid QRS complex in the second channel. Preferably this is accomplished by discerning if the data stored in the random access memory 84 obtained from the second channel was above a given threshold. (Col. 17, Lines 10-17).

As such, *Yomtov* discloses checking beat detection of a second channel when noise is sensed in the first channel. The Applicant respectfully submits that merely switching channels because of noise does not constitute verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

*Yomtov* further discusses the method used in Figs. 8A-B for verifying that a heart beat was detected:

For example, the microprocessor 92 analyzes the stored data for zero crossings at times which correspond to the ST segment of the ECG wherein, if the heart beat is a valid heart beat, the data would indicate a generally constant level. However, if there was noise in the first channel, the microprocessor will detect zero crossings resulting from signals of changing directions which would not normally occur during this interval. (Col. 16, Lines 61-68).

Accordingly, *Yomtov* discloses independently verifying that data collected on a particular channel is a heart beat by tracking zero crossings and using thresholds, not using one channel to verify that the other channel comprises a cardiac signal. For at least this reason, the Applicant respectfully submits that *Yomtov* does not disclose verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, as recited in independent claims 1 and 30.

Although the Examiner does not rely on the *Joo* reference to teach or suggest verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information, the Applicant respectfully submits that *Joo* does not contain such a teaching or suggestion, properly combinable with the *Yomtov* reference, to render independent claims 1 and 30 obvious.

For example, even if *Joo* provides multiple independent methods to detect the presence of a cardiac pulse in the patient ([0100]), such a disclosure does not constitute verifying that the separated signal is a cardiac signal using the separated signal and the non-electrophysiological cardiac source information.

Each of claims 2-19 and 31-36 depend from independent claims 1 and 30, respectively. Independent claims 1 and 30 are not obvious for at least the reason that the cited references fail to teach or suggest each and every limitation recited in each claim. Even though the Examiner does not rely on the *Wells* reference to teach or suggest any limitations of independent claims 1 or 30, *Wells* does not provide any teaching or

suggestion, properly combinable with the *Yomtov* and *Joo* references, to cure all of the deficiencies of the *Yomtov* and *Joo* references and render independent claims 1 and 30 obvious. Furthermore, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 30. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 2-19 and 31-36 are not made obvious by *Yomtov*, even in combination with *Joo* and further in combination with *Wells*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 1-19 and 30-36 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of the Applicant's invention, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.606PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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